EXHIBIT C

United States District Court
Eastern District of Michigan
Southern Division

David J. Mattila, as Personal Representative of the Estate of Milda E. Mattila, Deceased, et al.,

Plaintiffs,

v.

Centers for Medicare & Medicaid Services, Select Specialty Hospital – Ann Arbor, and **Blue Cross Blue Shield of Michigan**,

Defendants.
_____/

Civil No. 19-10446

Honorable Gershwin A. Drain
Mag. Judge Mona K. Majzoub

Defendant Centers for Medicare & Medicaid Services' Motion to Dismiss

Federal defendant, Centers for Medicare & Medicaid Services ("CMS"), by and through its attorneys, Matthew J. Schneider, United States Attorney for the Eastern District of Michigan, and Zak Toomey, Assistant United States Attorney, move this Court, pursuant to Federal Rule of Civil Procedure 12(b)(1), to dismiss Plaintiffs' claims against CMS for lack of subject matter jurisdiction.

Pursuant to Local Rule 7.1, CMS' counsel contacted plaintiffs' counsel to seek concurrence in this motion on October 29, 2019, but concurrence was not obtained.

Respectfully submitted,

Matthew J. Schneider
United States Attorney

s/ Zak Toomey
Zak Toomey
Assistant United States Attorney
211 W. Fort Street, Suite 2001
Detroit, Michigan 48226
(313) 226-9617
zak.toomey@usdoj.gov

Dated: October 29, 2019

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Brief in Support of Defendant Centers for Medicare & Medicaid Services' Motion to Dismiss

Issue Presented

Whether this court lacks subject matter jurisdiction over plaintiffs' claims when they "arise under" the Medicare Act and plaintiffs failed to exhaust their administrative remedies before filing suit in federal district court, which is required for any civil action brought under 42 U.S.C. § 405(g).

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I. INTRODUCTION

Plaintiffs in this action are Medicare beneficiaries[1] who were injured as a result of steroid injections that were found to be tainted with fungal meningitis. As a result of their injuries, each plaintiff received covered medical items and services for which Medicare paid. Plaintiffs all pursued and received recoveries for their injuries from a number of defendants, in two separate state and federal lawsuits. Under the Medicare Secondary Payer ("MSP") provisions of the Social Security Act, 42 U.S.C. § 1395y(b)(2), Medicare acts as a secondary payer of medical services for Medicare beneficiaries, meaning that when other insurance coverage (including a judgment or settlement involving a third party tortfeasor) is available to pay for such services, those sources must be utilized first, before Medicare coverage is available. In some circumstances, however, other insurance coverage is not immediately available or there is a question as to its availability. If it is the case that a primary payer is not expected to pay "promptly," Medicare will make a "conditional payment" for covered services so as to make sure those services are available to the beneficiary when needed. Once the primary payer's responsibility

[1] Nine of the plaintiffs are Medicare beneficiaries (Willard Mazure, Steven H. Smith, Jacqueline Fobare, Dolores Scull, Nora K. Clark, Betty L. Neidigh, Colleen Adkins, and Patricia Touzeau). One plaintiff, David J. Mattila, is the personal representative of the estate of a Medicare beneficiary (Milda E. Mattila). And one plaintiff is the estate of a deceased Medicare beneficiary (James Redmon). For purposes of simplicity, this brief refers to all plaintiffs as Medicare beneficiaries.

to make payment is finalized, the MSP provisions give Medicare a statutory right to reimbursement for its conditional payments.

Medicare beneficiaries, including the plaintiffs in this action, are entitled to appeal a demand for reimbursement of MSP conditional payments through a five-step administrative review process. In order to obtain judicial review in federal district court (the fifth step of the process), the beneficiaries must first exhaust their administrative remedies by proceeding through all four previous steps. In this case, plaintiffs have failed to take even the first step of the administrative review process. Because plaintiffs' claims "arise under" the Medicare Act and because the plaintiffs have failed to exhaust their administrative remedies prior to seeking review in federal district court, their claims against CMS should be dismissed for lack of subject matter jurisdiction.

II. FACTUAL AND LEGAL BACKGROUND

A. The NECC National Settlement and Plaintiffs' Decision to "Opt-Out" of the Subsequent MSP Settlement

This matter stems from a mass tort settlement relating to a national meningitis outbreak linked to steroid injections found to be tainted with fungal meningitis that were manufactured by the New England Compounding Pharmacy Inc., d/b/a New England Compounding Center ("NECC"). According to the Centers for Disease Control, there were at least 753 reported cases across 20 states, including 64 related deaths. *See Multistate Outbreak of Fungal Meningitis and*

Other Infections, available at https://www.cdc.gov/hai/outbreaks/meningitis.html (last reviewed October 30, 2015).

According to the Amended Complaint, plaintiffs are claimants in both federal and state court lawsuits that were filed in connection with the fungus-tainted steroid solutions, *In re: New England Compounding Pharmacy, Inc.*, Case No. MDL No. 1:13-md-2419-FDS (D. Mass.) and *Adair, et al. v. Michigan Pain Specialists PLLC, et al.*, Case No. 14-28156-NO (Livingston Cty. Cir. Ct., Mich.) (the "fungal steroid cases"). (*See e.g.,* ECF No. 13, 1st Am. Compl., PgID 3, 5-7 ¶¶ 9-10, 21-22, & 32-33).

As one result of the mass tort litigation pending against it, NECC filed for Chapter 11 bankruptcy in the United State Bankruptcy Court for the District of Massachusetts in December of 2012, *In re: New England Compounding Pharmacy, Inc.*, Case No. 12-19882-HJB (Bank. D. Mass.). On or about May 20, 2015, the bankruptcy court approved an NECC National Settlement, which established five NECC settlement funds for issuing settlement payments to claimants in connection with their tort claims in the fungal steroid cases. (Ex. A, Order Confirming Chapter 11 Plan). According to a December 2017 Status Report filed by the Tort Trustee in the MDL case, a total of 2,353 claims had been filed with the National Settlement Administrator, and approximately $149,402,166.22 in settlement funds had been disbursed. (Ex. B, December 2017 Status Report of Tort

Trustee, pages 3-4).

On or about September 20, 2016, in recognition of Medicare's statutory MSP rights to reimbursement from the NECC Settlement Funds (for conditional payments made on behalf of plaintiffs who were also Medicare beneficiaries), CMS, the NECC Tort Trustee, and various other parties entered into a settlement agreement ("MSP Settlement Agreement") designed to streamline the process by which Medicare-entitled claimants (such as plaintiffs) could resolve their MSP obligations to CMS. (Ex. C, MSP Settlement Agreement). In summary, the MSP Settlement Agreement provided a formula for calculating the amount of MSP payments that CMS would accept in full satisfaction of its reimbursement rights from the NECC Settlement Funds (the "Negotiated Lien Payment Amount"). (*See id.* at 2-3). Pursuant to the MSP Settlement Agreement, claimants would have the Negotiated Lien Payment Amounts automatically deducted from settlement payments that they received from the NECC Settlement Funds. (*Id.*). According to the NECC Settlement website, it appears that the NECC Tort Trustee has already made an initial and second payment to claimants from the NECC Settlement Funds, and it is anticipated that a third payment will be issued in 2-3 years. (*See Status of Claims Payments*, available at http://www.neccsettlement.com/Home/Documents (last visited October 28, 2019)).

However, entering into the MSP Settlement Agreement was optional, and

Medicare-entitled claimants (including plaintiffs) received notice letters giving them the right to opt-out of the settlement within 30 days. (*See* Attachment A-1 to Exhibit C, NECC Lien Letter Group II). The MSP Settlement Agreement stated that, if Medicare-entitled claimants opted-out, Medicare's contractor that administers the MSP program, the Benefits Coordination & Recovery Center ("BCRC"), would initiate and process individual MSP recovery cases:

> Once the recovery case is initiated by BCRC, attorneys may continue to work directly with BCRC to resolve an Opt-Out Medicare-Entitled Claimant's recovery claim. The process will include obtaining a Conditional Payment Notice ("CPN"), providing BCRC with final settlement details, and obtaining a recovery demand letter from CMS.

(Ex. C, at 5). In this case, all of the plaintiffs "opted out" of the MSP Settlement Agreement. Thus, they relinquished their rights to have their MSP obligations resolved based on the formula and Negotiated Lien Payment Amount detailed in the MSP Settlement Agreement. Accordingly, by default, they were left to process and resolve their MSP claims pursuant to the standard process set forth by the MSP statute and implementing regulations and guidance, which is detailed more fully below.

B. Medicare as Secondary Payer

Congress established the Medicare program in 1965 as Title XVIII of the Social Security Act (the "Medicare Act") in order to provide hospital and medical coverage to most persons over sixty-five years of age and to certain disabled

persons. *See Henry Ford Health Sys. v. Shalala*, 233 F.3d 907, 908 (6th Cir. 2000) (citing 42 U.S.C. § 1395c, *et seq.*). The Secretary of Health & Human Services administers the Medicare program through CMS. *See Walters v. Leavitt*, 376 F. Supp. 2d 746, 750 (E.D. Mich. 2005). CMS relies on a contractor, the Benefits Coordination & Recovery Center, to administer the MSP program.

The MSP provisions of the Medicare Act (sometimes referred to as the "MSP statute") make Medicare the "secondary" source of payment for health care services. *Id.* (citing 42 U.S.C. § 1395y(b)(2)). When a primary payer has not paid or cannot reasonably be expected to pay promptly for covered medical services, Medicare makes a conditional payment to ensure the beneficiary receives timely health care. *Id.* at 750-51 (citing 42 U.S.C. 1395y(b)(2)(A)(ii)). These payments are expressly conditioned on reimbursement to Medicare if and when the primary payer pays the beneficiary. *Id.* at 751 (citing 42 U.S.C. §§ 1395y(b)(2)(B)(i), 1395y(b)(2)(B)(ii)).

Specifically, the MSP statute provides that if the beneficiary receives payment from a primary payer, the beneficiary must reimburse Medicare "for any payment . . . with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service." 42 U.S.C. § 1395y(b)(2)(B)(ii). Several things can demonstrate a primary plan's responsibility for payment, including "a judgment, a payment

conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means." *Id.* Pursuant to 42 C.F.R. § 411.22(b)(3), the term "by other means" includes "a settlement, award, or contractual obligation."

As pertinent to this case, a tortfeasor can be a "primary plan" (*i.e.*, a primary payer) under the MSP statute. *See Anderson v. Burwell*, 167 F. Supp. 3d 887, 897 (E.D. Mich. 2016). In other words, if a Medicare beneficiary sues a tortfeasor and seeks medical expenses as damages, and the parties settle the claim, the settlement demonstrates the tortfeasor's responsibility for those medical expenses, regardless of whether the tortfeasor admits liability. *Id.* (citing 42 U.S.C. § 1395y(b)(2)(B)(ii)). If the tortfeasor directly pays the settlement proceeds to the Medicare beneficiary, Medicare may seek reimbursement from the beneficiary. *Anderson*, 167 F. Supp. 3d at 897. Where Medicare claims reimbursement after settlement of a personal injury lawsuit, it reduces its claim to account for a proportionate share of attorney's fees and other costs of procuring the award. *See* 42 C.F.R. § 411.37.

In addition, it is the practice of the BCRC to send out periodical letters to beneficiaries listing conditional payments identified to date (sometimes referred to as "conditional payment letters or "conditional payment notices"). (*See generally*

Conditional Payment Information, available at https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Attorney-Services/Conditional-Payment-Information/Conditional-Payment-Information.html (last visited Oct. 24, 2019)). However, Medicare's legal right to recover conditional payments does not exist until the beneficiary actually receives payment from a primary plan. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii). Furthermore, it is the final demand letter for payment (and not any conditional payment letters) that is appealable through the administrative appeal process detailed below. Finally, if there are additional recoveries received from the beneficiary (such as new settlement payments), then the BCRC will recalculate the demand amount due.

C. Administrative Exhaustion and Judicial Review

A beneficiary may appeal a demand for reimbursement of MSP conditional payments by following the administrative review process set forth in 42 U.S.C. § 405(b), after which judicial review is permitted in accordance with 42 U.S.C. § 405(g). *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. §§ 405.900 *et seq.* & 405.1000 *et seq*.

There are five discrete steps to the administrative appeal process. First, the beneficiary may ask the MSP contractor to make a redetermination of the demand letter. 42 U.S.C. § 1395ff(a)(3)(B)(i); 42 C.F.R. § 405.940. Second, if dissatisfied with the contractor's redetermination, the beneficiary may seek a reconsideration

conducted by a separate, qualified independent contractor ("QIC"). 42 U.S.C. § 1395ff(b)-(c); 42 C.F.R. § 405.960. Third, if the beneficiary disagrees with the reconsideration determination issued by the QIC, he or she may seek a hearing before an administrative law judge ("ALJ"). 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1002. Fourth, a dissatisfied beneficiary may seek review of an adverse ALJ decision by the Medicare Appeals Council ("MAC"). Fifth, and finally, upon receipt of an adverse decision from the MAC, the beneficiary may seek judicial review from the relevant Federal district court pursuant to 42 U.S.C. § 405(g) and 42 U.S.C. § 1395ff(b)(1)(A); s*ee Heckler v. Ringer*, 466 U.S. 602, 607 (1984) (noting that the decision of the MAC is the Secretary's final decision for purposes of any judicial review in federal district court).

As discussed more fully below, all of plaintiffs' claims "arise under" the Medicare Act, thus making them subject to the Medicare Act's channeling provisions, which require administrative exhaustion. Plaintiffs have failed to exhaust their administrative remedies with respect to any of the demands for payment made by CMS or its contractor under the MSP statute. Therefore, this Court lacks subject matter jurisdiction over plaintiffs' claims and should dismiss them.

III. APPLICABLE STANDARD

"A Rule 12(b)(1) motion for lack of subject matter jurisdiction can challenge the sufficiency of the pleading itself (facial attack) or the factual existence of subject matter jurisdiction (factual attack)." *Cartwright v. Garner*, 751 F.3d 752, 759–60 (6th Cir. 2014) (citing *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994)). "A facial attack goes to the question of whether the plaintiff has alleged a basis for subject matter jurisdiction, and the court takes the allegations of the complaint as true for purposes of Rule 12(b)(1) analysis," while "[a] factual attack challenges the factual existence of subject matter jurisdiction." *Id.* "In the case of a factual attack, a court has broad discretion with respect to what evidence to consider in deciding whether subject matter jurisdiction exists, including evidence outside of the pleadings, and has the power to weigh the evidence and determine the effect of that evidence on the court's authority to hear the case." *Id.* When a 12(b)(1) motion is made, the plaintiff has the burden of proving the existence of subject matter jurisdiction in order to survive the motion. *Siding & Insulation Co., Inc. v. Acuity Mut. Ins. Co.*, 754 F.3d 367, 369 (6th Cir. 2014); *Moir v. Greater Cleveland Reg. Transit Auth.*, 895 F.2d 266, 269 (6th Cir. 1990).

IV. ARGUMENT

District courts are courts of limited jurisdiction. Actions are presumed to lie outside of the court's jurisdiction and the burden is on the party asserting

jurisdiction to establish that the matter lies within the court's authority. *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994). As set forth more specifically below, plaintiffs' amended complaint should be dismissed because they have failed to establish that this court has subject matter jurisdiction. Because plaintiffs' claims arise under the Medicare statute, plaintiffs must meet that statute's jurisdictional requirements before judicial review is authorized. Because none of the plaintiffs have exhausted their administrative remedies in this matter, they have failed to establish the prerequisites for this court's subject matter jurisdiction. Absent administrative exhaustion, none of the relief sought by plaintiffs is available.

A. Plaintiffs' Claims "Arise Under" the Medicare Act

A claim arises under the Medicare Act if "'both the standing and the substantive basis for the presentation' of the claim[] is the Social Security Act." *Heckler v. Ringer*, 466 U.S. 602, 615 (1984) (quoting *Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975)); *Giesse v. Sec'y of Dept. of Health & Human Servs.*, 522 F.3d 697, 702 (6th Cir. 2008). This is a "broad test." *Heckler*, 466 U.S. at 615 (1984); *see also Bodimetric Health Servs., Inc. v. Aetna Life & Cas.*, 903 F.2d 480, 483 (7th Cir. 1990) ("the Supreme Court has instructed us to read the term 'arising under' broadly").

It is clear from the Amended Complaint that all of plaintiffs' claims against CMS "arise under" the MSP provisions of the Medicare Act. Plaintiffs were all Medicare beneficiaries at the time of their injuries, and Medicare paid for services related to those injuries. Plaintiffs then became claimants in tort actions that sought recoveries for those same injuries. Now, plaintiffs have received or anticipate receiving settlement payments in connection with these injuries. (*See e.g.*, ECF No. 13, 1st Am. Compl., at PgID 3, 6, 9 ¶ ¶ 11-12, 23-24, 41). Thus, CMS has a statutory right to be reimbursed for Medicare's conditional payments. Through its contractor, the BCRC, and pursuant to 42 C.F.R. § 411.37, CMS has determined and demanded repayment of its conditional payments from plaintiffs, based on the amount of the recoveries that they have reported receiving.

Each plaintiff in this action makes separate factual allegations and lodges separate arguments about the appropriate calculation of Medicare's demand amount. Rather than participating in the administrative appeal process that is designed to adjudicate such matters, plaintiffs ask this court to step in and save them from the administrative process. However, both the "standing and the substantive basis" of plaintiffs' claims is the Social Security Act. *Heckler*, 466 U.S. at 615 (1984). Courts have previously recognized that claims "arise under" the Medicare Act when they derive directly from Medicare's determination that it is entitled to certain conditional payments under the MSP statute. *See, e.g.*, *Walter*

v. Leavitt, 376 F. Supp. 2d 746, 755 (E.D. Mich. 2005) (concluding that plaintiffs' claims "arise under" the Medicare Act because "[i]n essence, Plaintiffs are seeking a determination of the amount of reimbursement that [CMS] will seek under its subrogation rights created by the Medicare Act's MSP provisions"); *see also Wetterman v. Sec'y, Dept. of Health and Human Servs.*, No. 2:18-cv-85, 2019 WL 3208130, at * 4 (S.D. Ohio July 16, 2019) (noting that there would be no claim against CMS without the plaintiff's underlying claim for medical benefits, which "undoubtedly arises" under the MSP Act); *Bird v. Thompson*, 315 F. Supp. 2d 369, 374 (S.D.N.Y. 2001) (finding that a challenge to Medicare's right to reimbursement under the MSP Act was a claim arising under the Medicare Act). Accordingly, plaintiffs' claims against CMS "arise under" the Medicare Act and thus are subject to the channeling requirements of 42 U.S.C. § 405(g), (h).

As incorporated into the Medicare Act by 42 U.S.C. § 1395ii, 42 U.S.C. § 405(h) provides, in relevant part, that: No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or government agency except as herein provided. No action against the United States, the Secretary [of Health and Human Services] or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter. Such jurisdiction is granted only by 42 U.S.C. § 405(g), which provides that "[a]ny individual, after any final decision of the [Secretary] made

after a hearing to which he was a party . . . may obtain a review of such decision by a civil action commenced within sixty days after the mailing . . . of notice of such decision . . . .” (emphasis added). Thus, according to the Medicare Act, judicial review is available in federal court only after a dissatisfied claimant has obtained a “final decision” of the Secretary. As discussed more specifically below, plaintiffs have not even alleged that they have begun to access the statutory, five-level administrative appeal process, much less obtained a final decision of the Secretary that can be appealed to federal court. Plaintiffs have completely failed to exhaust their administrative remedies, making judicial review unavailable due to this court’s lack of subject matter jurisdiction.

B. Plaintiffs Have Failed to Exhaust Their Administrative Remedies

Under the Medicare Act, there is only one way for a party to establish federal court jurisdiction for any claim arising under the Act—by presenting all claims to the agency during the administrative appeals process and exhausting all available administrative remedies. *See* 42 U.S.C. § 405(g).

In their Amended Complaint, plaintiffs fail to cite any statute establishing jurisdiction. Rather, they simply allege that “jurisdiction [is] properly vested in this Court by virtue of Defendant CMS having removed this action . . . and by virtue of Plaintiffs bringing claims against CMS / Medicare, an agency of the United States.” (ECF No. 1, 1st Am. Compl., PgID 2, ¶ 4). To the extent that plaintiffs are

alleging that subject matter jurisdiction exists due to a federal question or diversity of the parties, § 405(h) precludes these types of subject matter jurisdiction. *See Giesse v. Sec'y of Dept. of Health & Human Servs.*, 522 F.3d 697, 702 (6th Cir. 2008) (federal question jurisdiction); *Bodimetric Health Servs., Inc. v. Aetna Life & Cas.*, 903 F.2d 480, 489–90 (7th Cir. 1990) (diversity jurisdiction); 42 U.S.C. § 405(h); 42 U.S.C. § 1395ff(b)(1)(A). Plaintiffs can only establish subject matter jurisdiction under § 405(h) if they demonstrate that they have exhausted their administrative remedies.

Administrative exhaustion under § 405(g) requires two prerequisites. *See* 42 U.S.C. § 405(g); *S. Rehab. Group, P.L.L.C. v. Sec'y of Health and Human Servs.*, 732 F.3d 670, 678 (6th Cir. 2013). First, the party must actually complete all five steps of the Medicare administrative appeals process described in 42 U.S.C. § 1395ff and 42 U.S.C. § 405(g). The second prerequisite is a "nonwaivable and nonexcusable requirement that an individual present a claim to the agency before raising it in court." *S. Rehab. Group*, 732 F.3d at 678 (quoting *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 15 (2000)). That is, "both presentment of claims *and* the exhaustion of administrative remedies is required." *Manakee Prof'l Med. Transfer Serv., Inc. v. Shalala*, 71 F.3d 574, 580 (6th Cir. 1995) (emphasis in original). Here, plaintiffs cannot satisfy either prerequisite for establishing subject matter jurisdiction. Nowhere in their Amended Complaint do

plaintiffs allege that they obtained an adverse decision from the Medicare Appeals Council, or completed even one of the five steps to the administrative review process. Nor do they allege that they previously presented the claims to the agency before raising it in court. Accordingly, plaintiffs' failure to exhaust their administrative remedies is fatal to their claims and divests this Court of subject matter jurisdiction.

C. Plaintiffs May Not Waive Administrative Exhaustion

With regard to exhaustion, the clear statutory exhaustion requirement embodied in the Medicare Act has led to countless decisions consistently holding that district court jurisdiction is lacking in the absence of exhaustion of administrative remedies. *Giesse v. HHS*, 522 F.3d 697, 702-03 (6th Cir. 2008) (§ 405(h) clearly prohibits judicial review where claims arise under Medicare Act); *Cathedral Rock of North College Hill, Inc. v. HHS*, 223 F.3d 354, 359 (6th Cir. 2000); *Manakee Professional Med. Trans. Serv.*, 71 F.3d at 578-79; *Michigan Ass'n of Indep. Clinical Labs v. Shalala*, 52 F.3d 1340, 1348-51 (6th Cir. 1994); *Farkas v. Blue Cross & Blue Shield of Michigan*, 24 F.3d 853, 860 (6th Cir. 1994); *Westchester Management v. DHHS*, 948 F.2d 279, 282 (6th Cir. 1991); *Ivanchenko v. Burwell*, 2016 WL 699550 at *3 (N.D. Ill. 2016) (Docket No. 16-C-9056).

Notwithstanding the foregoing, there are very limited instances in which waiver of the exhaustion requirement may be appropriate. The Supreme Court

articulated a three factor test for courts to use when determining whether to waive exhaustion. *See Bowen v. City of New York*, 476 U.S. 467 (1986). The three factors of the test are: 1) whether the claim in the district court is collateral to the claim for benefits; 2) whether irreparable harm would follow if exhaustion were not waived; and 3) whether exhaustion would otherwise be futile. *Id.* at 483-87; *Matthews v. Eldridge*, 424 U.S. 319 (1976).

Here, plaintiffs fail to satisfy any of the three factors set forth by the Court in *Bowen*. First, plaintiffs' claims are not collateral to their claim for Medicare benefits. As demonstrated above, plaintiffs' claims in their Amended Complaint resolve around the proper amount of conditional payments that are owed to Medicare under the MSP statute. Plaintiffs have alleged nothing that would support this court's determination that the heart of their claims is collateral to their substantive claims under the Medicare Act. Second, plaintiffs have made no allegation (much less showing) that they would suffer irreparable harm if they were to follow the administrative review process and contest BCRC's demand letters through the normal course. Moreover, plaintiffs themselves made the decision to "opt out" of the MSP Settlement Agreement, and thus, they cannot claim to suffer "irreparable harm" for taking an avenue which they, themselves, chose. Finally, none of the plaintiffs have demonstrated that they completed even the first step of the administrative appeal process (*i.e.*, a request that the MSP

contractor make a redetermination of the demand amount). Thus, plaintiffs cannot make a serious claim of futility. In the Sixth Circuit, the question of whether it would be futile to exhaust administrative remedies has been distilled into whether the plaintiff "is simply being required to seek review first through the agency or is being denied altogether the opportunity for judicial review." *Cathedral Rock*, 223 F.3d 354, 360 (6th Cir. 2000). Here, plaintiffs are not being denied their opportunity for judicial review, but they must following necessary steps to receive it. It should not fall upon this court to excuse plaintiffs from their own failure to exhaust.

V. CONCLUSION

For all of the foregoing reasons, plaintiffs' Amended Complaint should be dismissed for lack of subject matter jurisdiction.

Respectfully submitted,

Matthew J. Schneider
United States Attorney

s/ Zak Toomey
Zak Toomey
Assistant United States Attorney
211 W. Fort Street, Suite 2001
Detroit, Michigan 48226
Phone: (313) 226-9617
E-mail: zak.toomey@usdoj.gov

Dated: October 29, 2019

Certificate of Service

I hereby certify that on October 29, 2019, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system, which will send notification to the registered ECF recipients.

s/Zak Toomey
Zak Toomey
Assistant U.S. Attorney

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

DAVID J. MATTILA, as Personal Representative of the Estate of MILDA E. MATTILA, Deceased, WILLARD MAZURE, STEVEN H. SMITH, JACQUELINE FOBARE, DOLORES SCULL, NORA K. CLARK, BETTY L. NEIDIGH, COLLEEN ADKINS, Estate of JAMES REDMON, PATRICIA TOUZEAU, and PAUL WHITE, JR,

Plaintiffs,

v.

CENTERS FOR MEDICARE & MEDICAID SERVICES, SELECT SPECIALTY HOSPITAL – ANN ARBOR, and BLUE CROSS BLUE SHIELD OF MICHIGAN,

Defendants.

Case No. 2:19-cv-10446
Hon. Gershwin Drain
Mag. Judge Mona K. Majzoub

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANT MEDICARE & MEDICAID SERVICES' MOTION TO DISMISS

INTRODUCTION

Plaintiffs agree they are Medicare beneficiaries who were injured as a result of steroid injections found to be tainted with fungal meningitis. Plaintiffs also agree that each Plaintiff did receive covered medical items and services for which Medicare paid. Though each Plaintiff filed lawsuits for the tainted injections, neither Plaintiff Mattila nor Plaintiff Mazure have received any recovery because Medicare has not resolved with Plaintiffs its lien interest / anticipated right of reimbursement[1]. Plaintiffs Mattila and Mazure have actually attempted to resolve Medicare's claim of lien, to no avail, for a couple of years. Both Mattila and Mazure have complied with CMS / Medicare's administrative requests / process to no avail, and both Plaintiffs are waiting on CMS to "make a move". Because of the unique circumstances of these cases, whereby Plaintiffs must first resolve their Medicare liens *before* they are entitled to any proceeds, Plaintiffs Mattila and Mazure have no other option but to seek judicial intervention. Even if the administrative remedies

[1] Under the terms of the settlement, proceeds cannot be tendered to claimant / Plaintiff until CMS/Medicare provides written notification to the NECC Tort Trustee that it has resolved its claim of lien with Plaintiff. [See DE 20-4, Page ID 194-95]. Plaintiffs Mattila and Mazure have had their anticipated settlement proceeds tied up for years because Medicare has not resolved its liens.

argued by Defendant *did* apply, neither Mattila nor Mazure can avail themselves of same because they have yet to receive any settlement proceeds, or even a demand for reimbursement from Defendant[2]. Therefore, Mattila and Mazure are stuck in a perpetual holding pattern, with no administrative recourse. Defendant's actions placing Plaintiffs in this position therefore amount to a "final" agency action which is actionable under the Administrative Procedures Act under 5 USCA §704.

As to the remaining Plaintiffs, they did receive some or all of their settlement proceeds, and also paid off their Medicare liens in full, only to have Medicare re-assert the same lien on the same settlement. Defendants' agreement to resolve its lien interests and acceptance of payment in full amounts to a final agency action under both the administrative remedies cited by Defendant and the APA relied upon by Plaintiffs.

Plaintiffs' action for declaratory judgment seeks court intervention to compel Medicare to finally resolve its claim of lien with Plaintiffs Mattila and Mazure so

[2] As conceded by Defendant, Medicare's "legal right to recover conditional payments does not exist until the beneficiary actually *receives payment* …". [DE 20, Page ID 131]. And as further conceded by Defendant, Plaintiffs cannot get to the first step of the five-step administrative appeal process until Defendant issues a demand for reimbursement (the first step of the appeal process is a request for redetermination of the demand letter. Plaintiffs have never received a demand letter) [DE 20, Page ID 131].

that these poor victims can finally receive their proceeds, and to issue an order declaring that Plaintiffs have paid their Medicare liens in full, and preventing Medicare from reasserting the already resolved lien interests.

Defendant Medicare's Motion to Dismiss argues that Plaintiffs' action for declaratory judgment should be dismissed because Plaintiffs' failed to exhaust their administrative remedies under the Medicare Act. Defendants' Motion should be denied because: (1) as to Mattila and Mazure, because Plaintiffs have not received any settlement proceeds[3], the administrative process for demand for reimbursement and any review and appeal thereof does not and cannot apply; (2) Plaintiffs request for judicial intervention is actionable under the APA 5 USC §704; and (3) regarding the other Plaintiffs, all administrative remedies have been exhausted as evidenced by each Plaintiff having already negotiated, resolved, and fully paid Medicare's lien interests.

[3] As conceded by Defendant, "Medicare's legal right to recover conditional payments does not exist until the beneficiary actually *receives* payment*"*. [Def Mtn Dismiss, DE 20, Page ID 131 (p 8 of Brief)]. Plaintiffs are caught in a perpetual holding pattern. Plaintiffs cannot even trigger the administrative remedies until payment is received, but cannot receive payment until CMS agrees in writing its claim of lien has been resolved. Thus, CMS has entered a "final" decision which triggers this court's jurisdiction.

ARGUMENT

A. PLAINTIFFS MATTILA & MAZURE

Plaintiffs are claimants / parties to the mass tort settlement relating to the national meningitis outbreak linked to steroid injections later found to be tainted with fungal meningitis. One of the primary defendants was the manufacturer of the tainted solution, New England Compounding Pharmacy (NECC). Most of the claimants suffered devastating, longstanding, residual injuries. The number of claimants and the amount of damages presented forced NECC, to file for bankruptcy. A settlement was ultimately arrived at in the bankruptcy court, but the amount of available proceeds was nowhere near the amounts needed to reasonably compensate all 1,300 claimants. The limited amount of available proceeds to compensate all affected claimants was further compounded by the fact that most claims were subject to significant liens filed by insurance companies and CMS. In a lot of cases, the lien amounts exceeded the claimant's expected recovery. Thus, the settlement amounts allocated to each claimant amounted to only a fraction of the claimant's full claim for damages.

In an effort to find an equitable solution to the significant lien interests being asserted on already significantly compromised settlements/ recoveries, the NECC Tort Trustee, and representatives for the affected insurance companies and CMS agreed to a special lien reduction formula under which claimants could resolve their liens. Under the lien reduction agreement, claimants were automatically subject to the benefits of the agreement unless they filed a signed "opt-out" form with the NECC Trustee by a certain date. Plaintiffs Mattila and Mazure never "opted out", as argued by Defendant, but rather were "forced out" of the lien agreement.

1. Estate of Milda Mattila

Milda Mattila received her fungus-tainted steroid injection in August 2013 at the Michigan Pain Specialists Clinic (MPSC) in Genoa Twp, Michigan. Ms. Mattila is a claimant in both the federal and state actions and is expected to receive a total gross settlement of $300,186.91. The liens asserted on Mattila's claim were, and are, well in excess of her anticipated recovery, to-wit: CMS asserted a lien interest on $367,828 in conditional payments, Select Specialty Hospital (SSH) asserted a

lien in excess of $500,000[4], and BCBS asserted a lien of $51,175. Under the lien reduction agreement, Mattila technically could have settled his CMS and Blue Cross liens for 21.5% of the gross settlement ($78,523). However, because SSH was asserting a lien well in excess of the entire settlement, (which was *not* subject to the reduction agreement), Mattila could not commit to paying $78,000 to resolve only part of the liens. Mattila had no choice but to opt-out of the agreement. Several months later, however, SSH was finally reimbursed by Medicare for its outstanding hospital charges (and because SSH accepted CMS payment, it no longer has a valid claim of lien). Had CMS paid those charges in the first place, Mattila could have opted-in on the CMS Lien Agreement and resolved both the BCBS and CMS liens for 21% of the gross proceeds.

The above notwithstanding, Plaintiff attempted to resolve CMS's lien interest in good faith. The relevant timeline of events is as follows:

- 01-23-17 – CMS (through contractor BCRC) sent conditional payment letter asserting conditional payments (and a lien interest thereon) in the amount of $267,678.04 [**Ex A**]

[4] Expenses incurred for long term, inpatient, residential care which CMS refused to pay for a significant period of time.

- 04-10-17 - Plaintiff requested CMS to compromise its lien interest by agreeing to the underlying lien reduction agreement. Details about the anticipated settlement, costs, and fees, were also provided to CMS [**Ex B**];

- 05-01-17 – CMS (through its contractor BCRC) sent letter advising Plaintiff's request for compromise of CMS's lien interest has been transferred (along with entire case file) to the CMS Chicago Regional Office and that "a staff member from the Regional Office will contact you, if needed, as they evaluate your request" [**Ex C**];

- 09-18-17 – NECC Settlement Trustee advised Plaintiff that CMS is still awaiting Chicago Regional Office to review Mattila's request for compromise [**Ex D**];

- 09-22-17 – CMS (through contractor BCRC) sent another conditional payment letter, this time identifying conditional payments of $367,828.72 [**Ex E**];

- 10-18-17 – Plaintiff sent letter requesting CMS / BCRC to identify the representative from the CMS Chicago Regional Office so that Plaintiff's counsel could get in contact with same. Plaintiff never received a response [**Ex F**];

- 11-10-17 – Plaintiff Milda Mattila passed away. Estate was set up and opened several months later in 2018;

- 08-09-18 – Plaintiff emailed another copy of Plaintiff's 04-10-17 Letter requesting CMS to compromise its lien interest to CMS Chicago Regional Rep Paul Jackson (not even knowing if Mr. Jackson was assigned to the Mattila matter). [**Ex G**].

To this day, Plaintiff Mattila has yet to receive any response from CMS Medicare regarding Plaintiff's requests to compromise or negotiate Medicare's lien. CMS has likewise never sent to Plaintiff a Conditional Payment Notice or a Determination Letter (a/k/a Recovery Demand Letter). Plaintiff's counsel was compelled to file this action because he has no person from Medicare with whom to negotiate or even discuss the at issue lien. Plaintiff Mattila (the Estate) cannot avail itself of any of the administrative remedies cited by Defendant because Plaintiff does not have standing to pursue even the "first level" of appeal as argued by Defendant. The first level of appeal is a request for redetermination of Medicare's initial determination. Plaintiff has never received an initial Determination Letter from Medicare. Plaintiff cannot request an appeal requesting a "Redetermination" if Plaintiff does not have an initial determination from which to appeal[5]. Plaintiff Mattila has been waiting 2 ½ years to resolve its claim with Medicare and still cannot even avail itself of the Level one appeal stage.

[5] To illustrate Plaintiff's point, attached as **Exhibit H** is Plaintiff Counsel's similar letter to CMS Medicare, requesting a compromise of Medicare's lien interest. Attached as **Exhibit I** is CMS / Medicare's response to that request, a Determination Letter as contemplated and required by the administrative process. The Court will note there is no such response or Determination letter for Mattila. Attached as **Exhibit J** is a 1st Level Appeal Form for a Request for Redetermination of CMS's original / underlying determination. Plaintiff Mattila has no standing to fill out that appeal form.

2. **Willard Mazure**

Plaintiff Mazure is also a claimant in the above referenced federal and state actions, who is expected to receive a total gross settlement of $365,224.44. The liens asserted on Mazure's claim are: (1) CMS $77,597.14 (in conditional payments); and (2) BCBS $161,727.94. Plaintiff has resolved Blue Cross's lien for $45,000. Mazure never signed an Opt-Out form to exclude himself from the CMS Lien Agreement. Rather, he was a "deemed opt-out", per the NECC Trustee[6]. Similar to Mattila, Plaintiff Mazure has not been able to receive a CMS response to his request for compromise of CMS's lien interest (on the basis that many of Medicare's alleged conditional payments are unrelated to his fungal meningitis diagnosis). The relevant timeline of events are as follows:

- 04-16-17 – Plaintiff requested CMS to compromise its lien interest. Information about settlement also provided;
- 05-01-17 – CMS (through its contractor BCRC) sent letter advising Plaintiff's request for compromise of CMS's lien interest has been transferred (along

[6] Subsequent to CMS and the Mass Tort parties agreeing to the Lien Agreement, the NECC Trustee sua sponte decided that Plaintiffs / Claimants whose claims were encumbered with three or more liens could not avail themselves of the Lien reduction agreements, and issued "Deemed Opt Out" Letters on behalf of these claimants. Mazure was a "deemed opt-out" because a third "bogus" lien was asserted by Rawlings Company. Rawlings later rescinded its bogus lien after Plaintiff requested it to produce an accounting of same. By the time Rawlings rescinded its lien, Mazure was already a "deemed opt-out" and kicked out of the lien reduction agreement.

with entire case file) to the CMS Chicago Regional Office and that "a staff member from the Regional Office will contact you, if needed, as they evaluate your request" [**Ex K**]. Plaintiff never received a response to this request for compromise.

- 04-17-19 – Plaintiff again requested CMS to compromise its lien interest, by reducing its conditional payment amount by the amounts which are unrelated to Mazure's fungal meningitis diagnosis. Information about anticipated settlement was also provided. [**Ex L**]

- 06-06-19 – CMS sent letter advising of it will accept $52,434.27 as payment in full for its recovery claim. This amount, however, was calculated by simply plugging in Plaintiff's settlement amount and attorneys fees, and failed to respond to Plaintiff's request to reduce the conditional payments by the unrelated expenses. Thus, CMS's "compromise" is not a compromise at all, and expressly states it is not an "Initial Determination". [**Ex M**].

- 06-18-19 – Plaintiff sent another letter to CMS asking it to respond to Plaintiff's Request for Compromise. Plaintiff has heard nothing back from CMS. [**Ex N**].

As in Mattila, Plaintiff Mazure is in a perpetual holding pattern and is without an initial determination letter from which to even file a "first appeal", notwithstanding Mazure having requested CMS to compromise or negotiate its lien interest since 2017.

3. **Medicare's Non-Responsiveness Has Created an Impasse Whereby Mattila and Mazure Have No Further Remedy or Redress, and Therefore Medicare's Actions Amount to a Final Agency Decision, which is Actionable Under the Administrative Procedures Act of 5 USCA §704**

As Plaintiffs have already shown above, Defendant's argument that this court has no jurisdiction because Plaintiffs' Mattila and Mazure failed to exhaust their administrative remedies under the Medicare Act, does not apply to the facts of this case.

First, under the Lien Resolution Agreement entered into between CMS and the Mass Tort parties, Medicare agreed to resolve its lien interests with the opt-out claimants through a process where CMS is required to resolve its lien interest prior to the claimant being entitled to any settlement proceeds [DE 20-4, PageID 195]. Neither Plaintiff has received a nickel in settlement proceeds. Medicare's legal right to recover conditional payments does not even exist under the Act until the beneficiary actually *receives* payment". [Def Mtn Dismiss, DE 20, Page ID 131 (p 8 of Brief)]. Second, Defendant has yet to issue an initial demand /

determination letter, notwithstanding Plaintiffs' request for compromise / negotiation requested more than two years ago. As Defendant concedes in its Brief, Plaintiffs cannot get to the first step of the five-step administrative appeal process until Defendant issues a demand for reimbursement (the first step of the appeal process is a request for redetermination of the demand letter. Plaintiffs have never received a demand letter) [DE 20, Page ID 131].

Plaintiffs submit their equitable action is permitted under 5 USC §704 of the Administrative Procedures Act, which allows judicial review of:

> … final agency action for which there is no other adequate remedy in a court is subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.

Under the APA, the Court is empowered to compel agency action unlawfully withheld or unreasonably delayed, and / or to set aside any agency actions contrary to law, regulation, or the evidence. 5 USC §706(1) & (2).

Medicare's apathy on these cases, as evidenced by its lack of response to Plaintiff's requests and lack of issuing any initial determination letter, leaves Plaintiffs without a remedy of their current predicament. Plaintiff Mattila tragically

died without ever seeing her proceeds, because she was waiting for Medicare to resolve its lien. Mazure has yet to see any of his proceeds because Medicare similarly refuses to respond to Plaintiff's requests to negotiate, compromise and resolve Medicare's lien. Medicare's actions / inactions amount to a final agency action from which Plaintiffs have no standing to appeal. Plaintiffs have standing under the APA to pursue a claim for judicial review of Medicare's actions relating to the at issue lien interests.

B. THE REMAINING PLAINTIFFS

In contrast to Plaintiffs Mattila and Mazure, the remaining Plaintiffs have already negotiated, resolved, and fully paid Medicare's lien interests on their respective claims. Medicare's attempt to reassert its lien interests are barred by res judicata and/or collateral estoppel, and have nothing to do with a failure to exhaust administrative remedies. In fact, Plaintiffs have completely exhausted their administrative remedies, as evidenced by the fact that Medicare's lien was settled and paid in full. To illustrate this point, Plaintiffs will address Plaintiff Fobare's Medicare lien. The relevant timeline for Plaintiff Fobare is as follows:

- 06-07-17 - Plaintiff Fobare contested CMS's $120,000 in conditional payments by pointing out diagnosis codes that were preexisting or did not relate to treatment from the injections. Anticipated settlement information is also provided. [**Ex O**].

- 06-09-17 – CMS sent a letter advising it reduced its conditional payments to $89,006.05, and issued a demand letter for $58,144.42 for satisfaction of its lien interest. [**Ex P**]

- Nov 2017 – Plaintiff sent a check to CMS for $58,144.42

- 11-27-17 – CMS sent another lien letter, asserting another lien for $8,986.90, within days of receiving Plaintiff's check paying the lien off in full. [**Ex R**]

- 02-02-18 – CMS sent letter advising it received payment in full and was closing out its case. [**Ex Q**].

- 08-10-18 – Plaintiff sent letter asking CMS to withdraw its re-asserted lien as Plaintiff fully resolved and paid off said lien [**Ex S**];

- 08-20-18 – CMS sent letter advising it will not withdraw its re-issued lien of $8,986.90. [**Ex T**].

Plaintiffs submit the remaining Plaintiffs also negotiated their liens with Medicare, paid them off in full, only to have Medicare turn around and re-assert another lien interest on the same claim.

Because CMS's lien interest was already negotiated and paid in full, any attempt to re-litigate is barred by res judicata and/or collateral estoppel and CMS's claim should be null and void.

E. CONCLUSION

For the reasons stated above, Defendant's Motion should be denied.

Respectfully submitted,

/s/ Todd J. Weglarz
Geoffrey N. Fieger (P30441)
Todd J. Weglarz (P48035)
Danielle L. Dezbor (P79488)
Fieger, Fieger, Kenney & Harrington, P.C.
Attorneys for Plaintiff
19390 W. Ten Mile Rd
Southfield, MI 48075
(248) 355-5555
t.weglarz@fiegerlaw.com

December 18, 2019

CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2019, I electronically filed Plaintiffs' Response to Defendant CMS's Motion to Dismiss with the clerk of the Court, using the ECF system which will send notification of such filing.

/s/ Danielle L. Dezbor
Danielle L. Dezbor

United States District Court
Eastern District of Michigan
Southern Division

David J. Mattila, as Personal Representative of the Estate of Milda E. Mattila, Deceased, et al.,

Plaintiffs,

v.

Centers for Medicare & Medicaid Services, Select Specialty Hospital – Ann Arbor, and **Blue Cross Blue Shield of Michigan**,

Defendants.

Civil No. 19-10446

Honorable Gershwin A. Drain
Mag. Judge Mona K. Majzoub

DEFENDANT CENTERS FOR MEDICARE & MEDICAID SERVICES' REPLY IN SUPPORT OF ITS MOTION TO DISMISS

Plaintiffs have not established subject matter jurisdiction. They do not dispute that their claims "arise under" the Medicare statute. Thus, their only avenue to this Court requires that they present all their claims to the agency first during the administrative appeals process, and that they exhaust all available administrative remedies. *See* 42 U.S.C. § 405(g). They have failed to do so; therefore, their claims lack jurisdiction. Plaintiffs' arguments that the Administrative Procedures Act (APA) creates jurisdiction and that CMS is estopped from seeking any further MSP payments are incorrect because the APA is not a jurisdictional statute and estoppel does not apply against the government absent proof of intentional affirmative misconduct and there is no such evidence in this case.

A. Plaintiffs Have Failed to Exhaust Their Administrative Remedies

The first step in the administrative review process is a "redetermination" appeal of the BCRC's demand letter. 42 U.S.C. § 1395ff(a)(3)(B)(i); 42 C.F.R. § 405.940. Plaintiffs complain that they have yet to receive demand letters with respect to Mattila and Mazure. However, Mattila and Mazure (as well as the remaining plaintiffs) must provide necessary settlement information before CMS can calculate appropriate demand amounts. This information includes the amount of the settlement payment, as well as any attorney's fees and any additional procurement costs paid by the beneficiary to obtain the settlement payment. CMS

requires this information because, by regulation, where Medicare seeks reimbursement after settlement of a lawsuit, it reduces its claim to account for a proportionate share of attorney's fees and other costs of procuring the award. *See* 42 C.F.R. § 411.37. Plaintiffs Mattila and Mazure have failed to furnish this required information; therefore, the agency is not improperly withholding agency action because plaintiffs have not provided the information necessary to begin the administrative process.

1. Plaintiff Mattila

The process to obtain a demand letter from CMS is set forth in every conditional payment letter received by Plaintiffs. (*See* ECF No. 24-6, at PageID.336–39). The conditional payment letter requests that Mattila "refrain from sending any monies to Medicare *prior to submission of settlement information and receipt of a demand/recovery calculation letter from our office*." (*Id.*) (emphasis added). Enclosed with the conditional payment letter was a blank "Final Settlement Detail Document" listing the information that the BCRC required in order to calculate the final amount due and issue a demand letter. The required information included not only the amount of the settlement but the "Attorney Fee Amount Paid by the Beneficiary" and any "Additional Procurement Expenses Paid by the Beneficiary." (*Id.* at PageID.339).

Mattila has failed to submit the required information. On April 10, 2017, she sent a letter attempting to compromise (or settle) her MSP obligations with Medicare. (ECF No. 24-3, at PageID.325–26). She re-sent that same letter via e-mail to CMS on August 9, 2018. (ECF No. 24-8, at PageID.345). Mattila's April 10, 2017 letter attached a document from the NECC Tort Trustee identifying the "Approved Initial Payment Amount" of $104,586.41, (*see* ECF No. 24-3, at PageID.326); however, neither the April 10, 2017 letter nor the August 9, 2018 email specified the amount of attorneys' fees or additional procurement expenses paid by the beneficiary. Upon receipt of this information from Mattila, the BCRC will calculate the final amount due to Medicare and issue a demand letter.

2. Plaintiff Mazure

Mazure has also failed to submit all of the required settlement and procurement information to the BCRC. On December 19, 2016, the BCRC sent Mazure a conditional payment letter identifying $77,597.14 in conditional payments. (*See* ECF No. 24-13, at PageID.385–88). On April 17, 2019, Mazure sent a compromise request to the BCRC. (*Id.* at PageID.362–65). Mazure provided the required attorneys' fees and costs information; however, Mazure did not provide the amount of the initial settlement payment. (*Compare id.* at PageID.363, 402) (identifying only the total estimated settlement payout of $365,224.44) *with* ECF No. 24-3, at PageID.325–26) (Mattila's letter attaching NECC National

Settlement letter identifying an "Approved Initial Payment Amount" of $104,586.41).[1] Mazure has yet to provide his initial settlement payment amount to CMS. Once he does so, CMS will issue a demand letter.

B. The APA Does Not Confer Jurisdiction on this Court

"The APA is not a jurisdiction-conferring statute" and "does not directly grant subject matter jurisdiction to the federal courts." *Haines v. Fed. Motor Carrier Safety Admin.*, 814 F.3d 417, 423 (6th Cir. 2016) (internal quotations and citations omitted). The APA only authorizes challenges to "final agency actions for which there is no other adequate remedy in court." 5 U.S.C. § 704.

For MSP matters, a "final agency action[]" is a decision from the Medicare Appeals Council ("MAC"), which is the last step of the administrative process. *See Heckler v. Ringer*, 466 U.S. 602, 607 (1984). Plaintiffs have not obtained a MAC ruling; therefore, there is no final agency action in this case. Additionally, plaintiffs have an adequate alternative remedy in the form of the administrative review

[1] In footnote 5 of their response, plaintiffs provide an example of receiving a demand letter from the BCRC after providing a "similar" compromise request letter to CMS. (ECF No. 24, at PageID.307, n.5). However, this letter (pertaining to Sally Roe) contains all of the required information necessary for the BCRC to calculate its demand amount: (1) the first settlement payment of $92,893.52; (2) the attorneys' fees of $30,646.97; and (3) all procurement costs of $952.28. (ECF No. 24-9, at PageID.347–48). Based on this information, the BCRC was issued a demand letter on March 29, 2017. (ECF No. 24-10, at PageID.350–55).

process, which they have not yet initiated. *See Heckler*, 466 U.S. at 604 ("the above respondents clearly have an adequate remedy under § 405(g) for challenging all aspects of the Secretary's denial of their claims . . ."). Accordingly, plaintiffs cannot establish jurisdiction under the APA.

C. CMS is Not Estopped From Recovering Settlement Proceeds

"Estoppel is an equitable doctrine which a court may invoke to avoid injustice in particular cases." *Michigan Exp., Inc. v. United States*, 374 F.3d 424, 427 (6th Cir. 2004). The government, however, "may not be estopped on the same terms as any other litigant." *Id.* (citing *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 60 (1984)). To estop the government, plaintiff bears the "very heavy burden" of demonstrating an "intentional act by an agent of the government" that constitutes "affirmative misconduct." *Id.*

Here, plaintiffs do not make any showing of intent or affirmative misconduct. Instead, they only argue that their MSP claims have already been "negotiated, resolved, and fully paid" and therefore, Medicare can no longer seek reimbursement from them. (ECF No. 24, PageID.312–14). As an initial matter, none of these plaintiffs have demonstrated that they exhausted their administrative remedies for such claims; therefore, even if their claims were true, they have not yet obtained jurisdiction for this Court's review under § 405(g). *See Heckler*, 466 U.S. at 607.

In addition, their claims are not true. Plaintiffs have received multiple settlement payments from the NECC Tort Trustee, and each payment triggers an obligation to reimburse Medicare. For example, on June 5, 2017, the BCRC issued a conditional payment letter to Fobare identifying $120,834.43 in conditional payments. (Ex. A, Condit'l Payment Ltr., at 2). On June 6, 2017, Plaintiff Fobare provided the information necessary to calculate its demand amount for the *first* settlement payment.[2] (Ex. B, Ltr. 6/6/17, at 3). On June 19, 2017, CMS issued a demand letter, reducing the total amount using the formula in 42 C.F.R. § 411.37. (ECF No. 24-17, at PageID.414–15). The BCRC calculated this demand amount based upon the *first settlement payment only*, not the total estimated amount of all settlement payments. (*See* ECF No. 24-17, at PageID.416) ("This letter relates only to money paid from your *current settlement* . . . . If, in the future, you receive additional consideration or compensation from any source related to this injury, incident, or illness, you must let us know.").

[2] Plaintiffs purport to attach a letter dated "06-07-17" as Exhibit O to its Opposition. (*See* ECF No. 24, at PgID 313; ECF No. 24-16, Exhibit O to Opposition, at PgID 409-412). However, Exhibit O is actually an earlier letter to the BCRC, dated April 6, 2017, which – similar to other letters written by the plaintiffs – does not contain all the information necessary for the BCRC to calculate a final demand amount. Thus, in order to show how the BCRC calculated the final demand amount contained in its June 9, 2017 demand letter, CMS has attached a copy of Plaintiff Fobare's June 6, 2017 letter as Exhibit B.

Fobare received a second settlement payment from the NECC Tort Trustee a short time later and, as a result, on November 27, 2017, the BCRC issued a new conditional payment letter to Fobare with an entirely new Case Identification Number. (*Compare* ECF No. 24-19, at PageID.427 (showing Case ID No. 20173 19000 00005 on November 27, 2017 conditional payment letter) *with* ECF No. 24-17, at PageID.414 (showing Case ID No. 20130 64090 01484 on June 19, 2017 demand letter). Therefore, plaintiffs have not "fully paid" their MSP claims.

CONCLUSION

Plaintiffs' Amended Complaint should be dismissed for lack of subject matter jurisdiction because they failed to exhaust their administrative remedies before filing suit in this Court as required by 42 U.S.C. § 405(g).

Respectfully submitted,

Matthew Schneider
United States Attorney

/s/ Zak Toomey
Zak Toomey (MO61618)
Assistant U.S. Attorney
211 W. Fort Street, Suite 2001
Detroit, Michigan 48226
(313) 226-9617
zak.toomey@usdoj.gov

Dated: January 17, 2020

Certificate of Service

I hereby certify that on January 17, 2020, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system, which will send notification to the registered ECF recipients.

s/Zak Toomey
Zak Toomey
Assistant U.S. Attorney